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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/917,858 | 07/31/2001 | Regina Geertruida Schoemaker | 147/50194 | 9455 |

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| EXAMINER | |
|---|---|
| CHANNAVAJJALA, LAKSHMI SARADA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1615 | |

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/917,858 | SCHOEMAKER, REGINA GEERTRUIDA | |
| | Examiner | Art Unit | |
| | Lakshmi S Channavajjala | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Receipt of response dated 9-20-04 is acknowledged.

Claims 1-5 are pending.

### *Response to Arguments*

Applicant's arguments filed 9-20-04 have been fully considered but they are not persuasive.

Lepran- Rejection under 35 USC 103(a):

Applicants argue that the there is misconception regarding the present invention or of the difference between the damage to heart tissue incurred subsequent to myocardial infarction (MI), on one hand, and the relevance of disclosures related to arrhythmias (Lepran) and or the treatment of congestive heart failure (CHF).

It is argued that the present record provides no linkage between either arrhythmias or congestive heart failure and inhibiting tissue damage after MI, which is clearly refuted by the declaration of Dr. Rupp. Applicants argue that there is no explicitly teaching or suggestion of a treatment for tissue damage following MI, particularly with the claimed compound, moxonidine. More particularly, applicants state that Lepran teaches application of moxonidine before MI to avoid arrhythmia whereas the claimed invention is directed to a method of inhibiting tissue damage following MI. Applicants also argue that office improperly equates "arrhythmia (dysfuntion)" and "damage (structural)" and argue that they are different. Applicants arguments have been fully considered but not found persuasive because instant claim 1 generally states "a method of treating a patient who has suffered a MI" and does not state that the method is directed to treating tissue damage alone after an MI. Thus, the claim allows for any and all conditions

after the occurrence of MI and very well includes arrhythmia, a condition also acknowledged by applicants, that follows MI. For this reason alone it is examiner's position that the rejection is deemed to be proper and examiner asserts that there is no misconception regarding instant invention ands the teachings of the prior art. Applicants further acknowledge that the Lepran does teach arrhythmia occurring after MI and suggest a treatment for the same with the claimed compound. With respect to the argument regarding the dosages of moxonidine taught by Lepran, instant claims do not specify any dosage and further, applicants own statement that only one dosage taught by Lepran had a significant effect on tissue damage is an admission that Lepran does suggest the claimed invention. Unlike applicants' argument, the pretreatment dosages of moxonidine (taught by Lepran) are not unpredictable because the same dosage of moxonidine (0.03 mg/kg) which applicants agreed as being effective in reducing tissue damage is also effective increasing the survival rate.

WO '241- Rejection under 35 U.S.C. 103(a):

Applicants argue that there is no linkage between congestive heart failure and damage subsequent to MI. It is argued that as described by Dr. Rupp the CHF is related to the weak or diminished function of heart muscle that may be caused by a wide variety of mechanisms and that reference is limited to improve the hemodynamic parameters associated with CHF, such as reducing blood pressure and is unrelated to the inhibition of tissue damage following MI. Applicants arguments have been considered but not found persuasive because the instant treatment includes events or conditions that occur subsequent to MI, which cause further myocardial damage. While instant claims do not specify any event and only recites 'in an amount effective for treating myocardial damage", instant specification instant post-MI treatment

encompasses preventing the development of myocardial heart failure. Accordingly, heart failure is one of the conditions that are covered by the instant general term "post-MI". Further '241 also states that CHF in turn leads to increased cardiac rate, myocyte necrosis and hypertrophy (equates to myocardial tissue damage), which is the same as instant tissue damage. WO '241 clearly teaches how the hemodynamic parameters are related to the above myocardial tissue conditions (also described in instant specification). Further, WO '241 also establishes the relation between cardiac output and the contractile state of heart (a function of myocardial muscles) and moxonidine is effective in regressing myocardial hypertrophy. Accordingly, it is examiner's position that WO '241 does teach events or conditions that are seen down stream of MI and suggests the claimed method of treatment.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM, M-F, except alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
January 11, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600